

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)) MDL No. 2740
PRODUCTS LIABILITY LITIGATION)
) SECTION: "H" (5)
THIS DOCUMENT RELATES TO:)
ALL ACTIONS)

CASE MANAGEMENT ORDER NO. 15
(AGREED ORDER REGARDING PATHOLOGY PROTOCOL FOR
PRESERVATION AND TESTING OF TISSUE SAMPLES TAKEN FROM
PLAINTIFFS AND HANDLING OF PLAINTIFFS' PATHOLOGY SLIDES)

The Court hereby Orders as follows:

1. Applicability of Order. The following procedures will govern the pathology materials for any Plaintiff in MDL No. 2740. To the extent that any biopsied tissue or pathology materials exist for any Plaintiff, Plaintiff will maintain and preserve the tissue samples and pathology in an appropriate manner that preserves it for examination, testing, and use by both parties, as set out herein. Non-trial-pool Plaintiffs shall only be subject to paragraphs 1-6 of this Order, unless they are later named as a trial pool Plaintiff.

2. Definitions. As set forth herein, the term "**pathology materials**" refers to any tissue sample collected from a Plaintiff's scalp, including but not limited to tissue obtained from punch biopsies, shave biopsies, and incisional biopsies, as well as slides made from tissue. As set forth herein, the term "**gross specimen material**" refers to any pathology materials that are not on a slide, including but not limited to the paraffin-embedded tissue block.

3. Request for Preservation of Pathology Materials. Within forty-five (45) days of Plaintiff having undergone a procedure related to her alleged injury, Plaintiff's counsel in such case shall send a Request for Preservation of Pathology Materials (attached

as **Exhibit A**) to the facility where the procedure occurred (unless such a request in a similar form has already been sent).

4. Notice of Existence of Specimen. Once a Plaintiff has undergone a biopsy or Plaintiff's counsel has otherwise learned of the existence of pathology materials, Plaintiff shall within sixty (60) days (within seven (7) days for trial pool Plaintiffs) supplement her Plaintiff Fact Sheet ("PFS") to advise Defendants of the existence of pathology materials and any additional responsive information resulting therefrom including:

- Section VII, Hair Loss History;

Hair Loss History

Question	No	Yes	Name of Healthcare Provider (First, M.I., Last)
Have you had a biopsy of your scalp to evaluate your hair loss problem?	<input type="checkbox"/>	<input type="checkbox"/>	

- Section IX, Document Requests and Authorizations;

Type of Document(s)	Yes	No	If No, who has the document(s)?
Pathology reports and results of biopsies performed on you related to your hair loss. <i>Plaintiffs or their counsel must maintain the slides and/or specimens requested in this subpart, or send a preservation notice, copying Defendants, to the healthcare facility where these items are maintained.</i>	<input type="checkbox"/>	<input type="checkbox"/>	

- Section VI.6 ("Have you ever received treatment for the injury you allege in this lawsuit?"), providing a copy of the request for preservation letter sent to the provider; and
- Section VI.7 – 8, to the extent applicable.

5. Apportioning and Preservation of Pathology Materials and Pathology

Slides. Each party is entitled to a representative, comparable, and approximately equal

portion of the gross specimen material. Either side may request such material, and any slides, from the healthcare provider or facility maintaining the same with notice to opposing Liaison Counsel. Upon request, if authorizations attached to the PFS are deemed insufficient by the healthcare provider or facility, Plaintiff shall provide defendants with valid authorizations for release of such materials or slides.

a. Whichever Party Obtains Material First Agrees to Reserve Half for the Other Party. To the extent that either side requests and obtains such material, that “obtaining” party agrees to maintain and preserve the gross specimen material. And that party agrees to reserve one-half of the pathology materials for sectioning by the other party. The obtaining party agrees to provide the other party with any slides obtained from the pathology materials within ten (10) business days after the slides are requested by the other party. Each party agrees to maintain the slides in an appropriate manner that preserves them for examination, testing, and use by both parties. In addition, the obtaining party agrees to provide the other party with the entirety of the remaining gross specimen material within ten (10) business days after it is requested by the other party.

b. Mutual Notification and Sharing of Slides from Remaining Non-Sectioned Materials. To the extent that either side creates slides from the remaining non-sectioned pathology materials (the gross specimen material), that party agrees to notify the other side and provide that party with the opportunity to examine such slides. Each side agrees to provide the other party with any newly created slides within ten (10) business days after the slides are requested by the party. Each side also agrees to maintain any such slides in an appropriate manner that preserves them for examination, testing, and use by both parties.

Each party shall be responsible for maintaining any slides they create in a manner that preserves them for trial. Either side shall be responsible for maintaining the gross specimen material upon its appropriate transfer to that side.

6. Maintaining Chain of Custody. The parties agree that Plaintiff and Defendants shall document the chain of custody for all pathology materials using the form attached as Exhibit A. A copy of the chain of custody shall be provided to the other party or the Court upon request. Plaintiff will complete and maintain chain of custody information for such pathology materials that are already in possession of Plaintiff or Plaintiff's representatives, and provide the same on request of Defendants. If a party provides the pathology materials to consulting experts retained on their behalf, such party shall continue to maintain the chain of custody form with the name, address, and receiving signature of the party to whom the pathology materials are sent. The parties may create a redacted copy of the chain of custody form that redacts the identifying information of any consulting expert or retained expert if the discovery of said expert's identity is premature under the applicable rules and the Court's Order and Reasons of November 1, 2018 (Rec. Doc. 4836).

7. Trial Plaintiff Selections – Express Sharing Dates. The parties recognize that both sides will require access to pathology materials or slides in anticipation of expert discovery deadlines. Therefore, notwithstanding the status of any pending requests or prior transfers under the provisions above, and unless the parties jointly make other arrangements, for cases subject to trial selection under Case Management Order No. 14 (Rec. Doc. 3064), or amendments thereof, Defendants shall transfer any pathology material or slides currently in their custody to Plaintiffs four weeks before Plaintiffs' applicable

General and Specific Expert Report deadline. Plaintiffs will maintain custody of such materials or slides from the date four weeks before Plaintiffs' applicable General and Specific Expert Report deadline up to and including the date such reports are due. On the date that Plaintiffs' General and Specific Expert Reports are due, they will also transfer to defendants' custody of any pathology material or slides, which shall remain in defendants' custody until the date of Defendants' General and Specific Expert Reports. Plaintiffs may request such pathology materials or slides for examination during the period for rebuttal reports only. The parties shall maintain custody of their respective slides and apportionments of gross specimen material during the pre-trial period, but may jointly arrange transfer or inspection at the maintaining parties' convenience. New slides created during pre-trial, but not disclosed to the other side may be excluded from evidence at trial.

New Orleans, Louisiana this 8th day of November, 2018.



HON. JANE T. MILAZZO
UNITED STATES DISTRICT JUDGE

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EXHIBIT A - CHAIN OF CUSTODY FORM

[Case Name and Number]

Released by:

Name:

Company/Organization:

Address:

Telephone Number:

Date:

Time:

Signature of Recipient:

ITEM DESCRIPTION (To Be Completed By The Sending Custodian)

Gross Description of Item (including date of surgery when material removed and slide numbers if applicable)	Photographed While in Your Possession (Yes/No)	Manner of Preservation (paraffin block, histology slides, loose and in liquid, etc.)	Size of Specimen	Other identifying marks or comments

Note any change of condition:

Received by:

Name: _____

Company/Organization: _____

Address: _____

Telephone Number: _____

Date: _____

Time: _____

Signature of Recipient: _____

EXHIBIT B

IMPORTANT – REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS

[Date]

Attn: [Facility & Department]

[Address]

Re: [Date of Anticipated Procedure and Case Caption]

Dear [Department]:

I represent the Plaintiff, Ms. [Plaintiff's first and last name] (your patient), and Defendants' Liaison Counsel, Douglas Moore and John Olinde, copied below represent the Defendants, Sanofi-Aventis U.S. LLC and Sanofi US Services, Inc. (Sanofi), in the above referenced lawsuit. There is no litigation pending against your facility or treating physician in this matter. I write to request that you preserve the pathology material from Ms. [Plaintiff's last name]'s procedure, performed by Dr. [physician's first and last name].

It is important that any pathology obtained during this upcoming procedure be preserved for future analysis. The parties request that you preserve the specimen(s) as follows:

1. Please preserve ***all*** explanted materials.
2. Please process the pathology specimens according to your usual practice for the creation of histology slides.
3. Please document the procedure and the retention of all pathology according to your usual practice.
4. Do not discard or destroy any pathology or documentation related to this procedure.

Very truly yours,

[Counsel for Plaintiff]

Counsel for Plaintiff

cc: Douglas Moore, Esq. (*Liaison Counsel for Defendants, Sanofi-Aventis U.S. LLC and Sanofi US Services, Inc.*)

John Olinde, Esq. (*Liaison Counsel for 505(b)(2) Defendants*)